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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,229	01/23/2004	Daniel Dube	MC073YCA	9131

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EXAMINER	
BALLS, ROBERT J	

ART UNIT	PAPER NUMBER
1625	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,229	DUBE ET AL.	
	Examiner	Art Unit	
	R. James Balls	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-22,25,26 and 29-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *30,31 and 33* is/are allowed.

6)☒ Claim(s) *2,5,11-18 and 25* is/are rejected.

7)☒ Claim(s) *3,4,6-10,19-22,26,29 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-36 are pending.

2. This application is continuation of PCT/CA03/01800 filed on November 19, 2003, which claims benefit of U.S. Provisional Application No. 60/428,611 filed on November 22, 2002.

3. Claims 2-22, 25-26, 29-36 are currently under examination. Applicants cancelled Claims 1, 23-24, 27-28 and added new Claims 30-36.

Double Patenting

4. The rejection of Claims 2, 5, 11-18, 20-22 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,677,351 is maintained. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The doctrine of double patenting seeks to prevent the unjustified extension of patent exclusivity beyond the term of a patent. The doctrine's policy is to assure the public that upon expiration of a patent it will be "free to use not only the invention claimed in the patent but also modifications or variants which would have been obvious to those of ordinary skill in the art at the time the invention was made." *In re Zickendraht*, 319 F.2d 225, 232, 138 USPQ 22, 27 (CCPA 1963) (Rich, J., concurring).

In the instant case, applicants claim a compound of formula (I) wherein Y is a carboxylic acid. Applicants prior patent, U.S. Patent No. 6,677,351, claims nearly identical compounds except that Y is a carboxylic ester. Alcohols are suggestive of

their simple esters. *In re Ward* , F.2d 1021 (CCPA 1964), 141 USPQ 227. Esters have been held prima facie obvious over their prior art free acids absent unexpected results. *Id*; *Ex parte Bergel et al.*,121 USPQ 522 (POBA 1949). Applicants' instant carboxylic acid derivatives are obvious variants of their earlier claimed compounds in U.S. Patent No. 6,677,351. Granting applicants a separate patent would extent their exclusive rights and improperly limits the public's access to obvious variations of formerly patented compounds.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory

double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of Claims 25-26 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement is maintained. Further, new Claims 34-36 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The rejection as applied to Claims 34-36 was necessitated by applicants' amendment to the claims. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The invention must be described, "with such clarity that the reader is assured that the inventor actually has possession

and knowledge of the unique composition that makes it worthy of patent protection." *University of Rochester v. G.D. Searle & Co., Inc.*, 249 F. Supp. 2d 216 (W.D.N.Y. 2003) *affirmed* 358 F.3d 916 (Fed. Cir. 2004). An adequate written description thus "guards against the inventor's overreaching by later claiming that which he did not invent, by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation." *Vas-Cath v. Mahurkar*, 935 F.2d at 1561 (Fed.Cir. 1991).

Claims 25-26 and 36 are drawn to a method of "preventing," "treating" or "enhancing" not less than 50 different conditions, many of which are broad classes of disorders encompassing many more diseases. The grouping of diseases fails to demonstrate a common shared characteristic, as there is no apparent relationship between the listed diseases. For example, the list includes ulcerative colitis and head injury. There is no apparent phosphodiesterase-IV activity that links these two seemingly unrelated diseases and no description in the specification explaining a relationship. Furthermore, the specification does not describe how inhibiting phosphodiesterase-IV allows one to "prevent" ANY of the listed diseases. The specification, on pages 25-29, provides evidence of a method of treating inflammation, especially allergic pulmonary inflammation. However, it implicitly states that the compounds were unable to prevent diseases. In the last sentence of page 27, under the heading, "ANTI-ALLERGIC ACTIVITY *IN VIVO*," the specification states that there was "less inflammatory damage in the lungs of animals treated with compounds of the examples." Thus, the claimed compounds were able to treat inflammation but not

prevent it. Note, however, that the compounds may be able to prevent the worsening or the reoccurrence of a disease. This, however, is encompassed in a method of treating a disease. In this case, after the disease developed, the compound provides relief from the disease and prevents its reoccurrence.

Claims 34-35 are drawn to a method of treating a disease "susceptible to treatment by inhibition of phosphodiesterase-4." This language is broad as it encompasses diseases currently recognized as treatable by phosphodisesterase-IV as well as diseases hereinafter discovered. Applicants clearly do not have possession of diseases not yet known to be linked with phosphodiesterase-IV inhibition. Furthermore, the limitation that the disease be "susceptible to treatment" by PDE-4 reaches beyond an actual cause-effect relationship.

6. Claims 25-26 and 32-36 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a method of treating inflammation, especially allergic pulmonary inflammation, does not reasonably provide enablement for treating or preventing all the diseases included in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with the breadth of these claims. Applicants explain in their April 7, 2006 response that their compounds have utility and cite *Cross v.Iizuka*, 224 USPQ 739 (CAFC 1985) to point out that *in vitro* testing is sufficient to meet the utility requirement. The present rejection is not, however, based on lack of utility but whether undue experimentation is required to

practice the invention as claimed (although *Rasmusson v. Smithkline Beecham Corp*, 413 F.3d 1318, 75 USPQ2d 1297 (Fed.Cir. 2005) has blurred the differentiation). In addition to addressing utility, *Cross v. Iizuka* speaks to enablement as it relates to determining dosage levels (not an issue in the instant rejection.) *Id.* The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The specification does not enable the skilled artisan to treat all the claimed diseases with one compound. For instance, the claims are drawn to methods of treating memory and inflammation (among other things). Different PDE-4 inhibitors treat different diseases depending on the structure of the compound. For example, Maschler et al., (U.S. Patent No. 5,321,029) provides PDE-4 inhibitors useable in treating memory loss. Flockerzi (U.S. Patent No. 6,306,869) provides structurally distinct PDE-4 inhibitors useable in treating inflammation disorders. Although both patents provide compounds that bind PDE-4, the compounds are structurally different and treat different disorders. Applicants' compounds all share an identical core structure. Based on their structural similarity, it is expected that they are effective in treating the same disease. If, however, certain modifications within the claimed genus were found to alter the compounds' activity so that some compounds in the genus have a different utility (i.e.

were capable of treating a different disease), applicants' are entitled to both methods as long as support is found in the specification specifically identifying which compounds treat which diseases.

The specification on page 27 describes an anti-allergenic assay conducted in vivo. The assay is an allergic pulmonary inflammation model. Guinea pigs were given an antigen challenge. One group of the pigs was given compounds of formula I while the other was given nothing. Then the inflammatory leukocytes of each group were compared. Guinea pigs treated with compounds of formula I showed less inflammatory damage in the lungs. Based on this data, the specification demonstrates possession and enablement of a method of treating allergic pulmonary inflammation.

Claims 34-35 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a method of treating allergic pulmonary inflammation, does not reasonably provide enablement for treating or preventing all the diseases included in the claim. Since the claims include diseases not yet known to be associated with phosphodiesterase-IV inhibition, the specification cannot be enabling for a method of treating such diseases.

Conclusion

7. Claims 30-31 are allowable.

8. Claims 3-4, 6-10, 19-22, 32 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. James Balls whose telephone number is (571) 272-7997. The examiner can normally be reached on Mon - Fri 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom McKenzie can be reached on (571) 272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business

Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R. James Balls
June 26, 2006

Celia Chang
Primary Examiner
Art Unit 1625